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POLICY TITLE: Flexi-Seal® Signal Fecal Management System (FMS): Assessment, Placement, and Management

DISTRIBUTION: Patient Care Services Nursing Policy & Procedure Manual

Effective Date: June 2012

POLICY: It is the policy of Jamaica Hospital to utilize a Fecal Management System for patients who are immobilized or bedridden and who is incontinent of liquid or semi-liquid stool or has uncontrolled diarrhea.

I. PURPOSE:
1. The Flexiseal Fecal Management System (FMS) is a temporary incontinence containment device, which consists of a soft silicone catheter that is inserted into the rectum to collect, contain, and divert fecal waste away from the patient’s perineal skin. A low-pressure balloon resides within the rectum and the catheter is connected to a disposable collection bag at the distal end.

II. INDICATIONS:
1. The principle indication for use of the FMS is the patient with liquid or semi-liquid stool, increased risk for skin and pressure ulcer development, and/or little or no bowel control (e.g., patients with C-difficile or induced diarrhea)

2. Consider use of the FMS in a patient who is immobilized or bedridden, is incontinent for liquid or semi-liquid stool or has uncontrolled diarrhea for 3-4 episodes, and requires skin care every 1-2 hours.

III. CONTRAINDICATIONS:
1. Sensitivity to or have had an allergic reaction to any components within the kit;
2. Lower large bowel or rectal surgery within the past year;
3. Severe rectal or anal stricture or stenosis, severe hemorrhoids
4. Suspected or confirmed rectal mucosa impairment, (e.g., Impaired sphincter tone severe proctitis, mucosa ulcerations);
6. Fecal impaction.
7. This product is not intended to be used for pediatric patients, unless otherwise deemed by MD/NP/PA as medically necessary.
8. This product does not create pressure greater than 1 PSI when retention balloon is inflated with up to 45 ml of water.

Caution with using the FMS should be considered in the following:
1. Anticoagulant Therapy
2. Low platelet count
3. Neutropenia

This product is not intended to be used for more than 29 consecutive days. If deemed necessary to continue use of FMS, a new order must be obtained with documentation for reason for extending such as the benefits outweighing the risks

IV. PROCEDURE:

1. Determine cause of diarrhea e.g. need for medication adjustment, use of laxatives or chemotherapy
2. Obtain an order from an MD/NP/PA before insertion
3. A digital rectal exam should be performed by a MD/NP/PA or RN to check for sphincter tone before insertion
4. Implement specific prevention measures according to the risk factors, particularly those measures related to moisture, as outlined by the Pressure Ulcer Prevention screen in EPIC.

V. PLACEMENT:

1. Obtain Flexi-Seal® package from Clean Utility.
2. Pre-assemble the system, remove air from the balloon and fill syringe with no more than 45 ml of water or saline (can use tap water).
3. Lube balloon before insertion.
4. Position patient in left-side lying position or other appropriate position.
5. Insert and position balloon beyond the external orifice/rectal sphincter and well inside the rectal vault before inflating.
6. Fill balloon until white bubble on white port “pops,” which is usually anywhere from 32-45 cc. Bariatric patients may require less fill as the weight of the adipose tissue may cause greater pressure on the rectal vault.
7. Check for proper positioning of the balloon against the rectal floor by gently pulling on the catheter.
8. Write date that the Flexi-Seal® is inserted on label provided and affix onto white tab located at the bottom of the beaded hanging strap.

VI. OBTAINING STOOL SAMPLE:
1. Use small gauge needless syringe and obtain sample via sample port

VII. DAILY MAINTENANCE:
1. Once in place, the balloon should be checked every 24 hours (or whenever repositioning the patient or at shift change) to ensure that the appropriate amount of water (35-45 cc) remains in the balloon. Additionally, ensure that the black line is visible. You can give the device a gentle tug to ensure it is in the rectal vault securely.
2. IRRIGATE at least every shift. This is to ensure tube patency and avoid excess stool building up and odor emanating from inside tubing.
3. If the FMS falls out, it can be cleaned and reinserted.
4. Small amount of seepage may be seen with use of FMS. Barrier ointment should be applied for prevention of peri-rectal skin irritation.
5. Dispose of bag using institutions protocol for disposal of infectious waste (always assume infectious waste)

VIII. TROUBLESHOOTING:
1. Excessive seepage/leakage may indicate stool that is too thick or that too much water is in the retention balloon. If excessive leakage occurs, withdraw 5 to 7 cc and irrigate with water ensuring that the water goes into catheter. Repeat if necessary until you observe fluid passing into catheter.
2. The catheter should be irrigated (q shift) and PRN. Leakage can occur from stool “caking” in the tubing or becoming too pasty and clogging lumen openings.

I. SAFETY/CORRECTIVE ACTIONS:
1. IF the patient develops any complications during use of the FMS (e.g., bleeding), NOTIFY MD and remove device.
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PATIENT/FAMILY EDUCATION:
2. Instruct the patient/family/significant other about the rationale for insertion of the FMS
3. Elicit patient/family/significant other participation in ongoing pressure ulcer prevention strategies.

DOCUMENTATION
1. Date and time of insertion of the FMS
2. Amount, color and consistency of fecal waste every shift
3. Condition of perineal and peri-rectal skin and interventions for maintaining integrity
4. Document date and time of insertion on the silicone catheter using label with permanent marker.

REFERENCES:
ConvaTec (2010) Flexi-Seal Signal FMS FAQs, Retrieved on September 26, 2012, 0/accessser/0/1607/1950/frequently-asked-questions.html

Approved: Chief Nursing Officer
Applicability: All Nursing Personnel

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